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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/782,061

02/18/2004

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11-11160

5751

7590 01/04/2007
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EXAMINER

BORIN, MICHAEL L

ART UNIT

PAPER NUMBER

1631

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

01/04/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/782,061

Applicant(s)

ZEMLA, ADAM T.

Examiner

Michael Borin

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 9-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02/18/2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 02/18/2004
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of Claims

Claims pending are 1-13.

Response to election of species requirement filed 10/10/2006 is acknowledged. Applicant elected method as directed to first molecule (as in claim 2), without traverse. Claims 8 is withdrawn from consideration as being drawn to a non-elected species.

Information Disclosure Statement

Applicants' Information Disclosure Statement filed 02/18/2004 has been received and entered into the application. Accordingly, as reflected by the attached completed copies of forms PTO-1449, the cited references have been considered.

Drawings

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because Figs 2,3,6 are illegible. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Objections

Claim 1: the phrase in the preamble "finding 3D similarities in protein the structure" is not clear; it seems that ""finding 3D similarities in protein structures of " is rather meant.

Claim 6 consists of two sentences. Please correct.

Claim Rejections - 35 USC § 112, second paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, 9-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is applied for the following reasons.

- A. Claim 1: It is not clear whether the three steps of "comparing" recited in the claim are conducted independently or sequentially.
- B. Claim 1: The step of using LGA_S analysis is vague and indefinite: specification, in the section defining the scoring function LGA_S (p. 17), fails to identify variables k, X, S(F), S(LCS),w* used in calculation of the scoring function; thus, the function is undefined.
- C. Similarly, the term "apply the transform" in claims 3,9 is vague and indefinite. The term "transform" is not defined by the claim. The specification, also, does not provide a standard for ascertaining the requisite composition, and one of ordinary skills in the art would not be reasonably appraised of the scope of the invention.
- D. Claim 1, last step: it is not clear what constitutes "the calculated alignment". The preceding steps of the claim are based on preexisting "structure information of

alignment" (first step of the claim) and no method step is directed to calculating alignment.

Further, it is not clear what is meant by "quality" of the calculated alignment, and what constitutes "complete information" about the quality of the alignment.

E. Claim 3, step b): the claim step contains two alternative steps, "verify" and "modify" an alignment. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 3 recites the broad recitation "modify", and the claim also recites "verify" which is the narrower statement of the limitation.

F. Claim 7: The term "preselected information" is not clear. There is no antecedent basis for the term – there is no "preselected information addressed in the preceding part of the claim.

Claim Rejections - 35 U.S.C. § 101(utility)

The following is a quotation of the 35 U.S.C. § 101:

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Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

5. The pending claims have been reviewed in light of the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 U.S.C. 112, first paragraph, "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001.

The examiner is using the following definitions in evaluating the claims for utility.
"Specific" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention.

"Substantial" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. The following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use and, therefore, do not define "substantial utilities":

A. Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved.

B. A method of treating an unspecified disease or condition. (Note, this is in contrast to the general rule that treatments of specific diseases or conditions meet the criteria of 35 U.S.C. § 101.)

C. A Method of assaying for or identifying a material that itself has no "specific and/or substantial utility".

D. A method of making a material that itself has no specific, substantial, and credible utility.

E. A claim to an intermediate product for use in making a final product that has no specific, substantial, and credible utility.

"Credible" - Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the applicant's assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

"Well-established" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art.

See also the MPEP at §§ 2107 - 2107.02.

Claims 1-7, 9-13 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

The claims are directed to a method of finding 3D similarities in protein structures. As a result of computational determination, regions having 3D similarity in two protein molecules are identified. However, such result lacks substantial utility as subsequent research is needed to identify the utility of finding such 3D similarities. Thus, Zu-Kang (reference submitted by applicant) teaches that studies based on superimposition of 3D structures are "bound to be misleading" (end of Abstract).

Structure/structure alignments are often used in the analysis of conserved features of protein folds. The basic idea is that structural equivalence of residues is linked to hidden energetic features or other general rules of protein architecture. In such studies, a database of related proteins is prepared which contains structurally related residues, and equivalent residue pairs are scanned for invariant or conserved features. Obviously, conclusions deriving from such studies can be misleading, as structure alignments are ambiguous. (p. 129)

There is a prevailing tenet that protein structures are more conserved than sequences. This requires that such structurally conserved pairs can be identified in a unique fashion. When alternative alignments exist which are indistinguishable in geometric terms, this task becomes difficult or impossible unless additional criteria are available that allow us to discriminate the set of evolutionarily related residue pairs from those pairs that are only geometrically equivalent. (p. 128)

Thus, even if a method provides a "complete information about the quality of calculated alignment" (which instant claims declare but the specification does not fully support), identification of significance of the determined similarity would require further research. As such, the claimed method lacks substantial utility.

Claim Rejections - 35 USC § 112, first paragraph.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, 9-13 are also rejected under 35 U.S.C. §112, first paragraph. Specifically, since the claimed invention is not supported by either a credible asserted utility or a well established utility, one skilled in the art would not know how to use the claimed invention.

In addition, due to ambiguity of the term "to transform", and variables used in determining the LGA_S score (see rejections under 35 U.S.C. 112, second paragraph, sections B)-C)), the specification is not enabling as one skilled in the art would not know how to make, and thus how to use, the invention as claimed.

Claim Rejections - 35 U.S.C. § 101 (non-statutory invention)

Claim 1-7, 9-13 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The following analysis of facts of this particular patent application follows the analysis suggested in the "Interim Guidelines for Examination of Patent Applications for

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Patent Subject Matter Eligibility”¹. Note that the text of the Guidelines below is italicized.

To satisfy section 101 requirements, the claim must be for a practical application of the § 101 judicial exception, which can be identified in various ways

- The claimed invention “transforms” an article or physical object to a different state or thing.*
- The claimed invention otherwise produces a useful, concrete and tangible result, based on the factors discussed below.*

In the instant case, the claimed invention does not “transform” an article or physical object to a different state or thing. This does not preclude the subject matter to be patentable as, for eligibility analysis, as

physical transformation is not an invariable requirement, but merely one example of how a mathematical algorithm [or law of nature] may bring about a useful application. If the examiner determines that the claim does not entail the transformation of an article, then the examiner shall review the claim to determine if the claim provides a practical application that produces a useful, tangible and concrete result. In determining whether the claim is for a “practical application,” the focus is not on whether the steps taken to achieve a particular result are useful, tangible and concrete, but rather that the final result achieved by the claimed invention is “useful, tangible and concrete.” The claim must be examined to see if it includes anything more than a § 101 judicial exception. If the claim is directed to a practical application of the § 101 judicial exception producing a result tied to the physical world that does not preempt the judicial exception, then the claim meets the statutory requirement of 35 U.S.C. § 101. If the examiner does not find such a practical application, the examiner has determined that the claim is nonstatutory. (Guidelines, p. 20)

The question is thus whether the final result achieved by the claimed invention is a result which satisfies all three criteria of being useful, and concrete, and tangible. In determining if the instant claims are useful, tangible, and concrete, the Examiner must determine each standard individually. For a claim to be “useful,” the claim must produce a result that is specific, substantial, and credible. For a claim to be “tangible,” the claim must set forth a practical application of the invention that produces a real-world result. For a claim to be “concrete,” the process must have a result that can be

¹ Available at http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/guidelines101_20051026.pdf

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substantially repeatable or the process must substantially produce the same result again.

Furthermore, the useful, tangible, and concrete result must be either explicitly recited in the claim itself or inherently flow through therefrom, rather than merely addressed in the specification.

In addition, a claim must be limited only to statutory embodiments - thus, if the claim is broader than the statutory embodiments of the claim, the Examiner must reject the claim as non-statutory.

For an invention to be "useful" it must satisfy the utility requirement of section 101, i.e., it has to be (i) specific, (ii) substantial and (iii) credible. As discussed in the utility rejection above, the invention does not satisfy the criteria of utility requirements as not being substantial. Therefore, the claims are rejected as non-statutory for failing to comply with 35 USC 101, i.e., not providing a useful, concrete and tangible result.

If the specification discloses a practical application of a § 101 judicial exception, but the claim is broader than the disclosure such that it does not require a practical application, then the claim must be rejected. In the instant case, the claims encompass embodiments of the computational method wherein either all three steps of comparing are done independently one from another, or these steps can be performed on unrelated parts of the protein structures. Such embodiments of the method as claimed are not viewed as directed to any practical application.

Thus, as the claims do not recite a "useful" result, the claimed method is not statutory.

Claim Rejections - 35 USC § 102.

The instant claims are drawn to method of finding 3D similarities in protein structures of a first molecule and a second molecule. The method comprises providing preselected information regarding the first molecule and the second molecule, comparing the first molecule and the second molecule using Longest Continuous Segments (LCS) analysis, comparing the first molecule and the second molecule using Global Distance Test (GDT) analysis, and comparing the first molecule and the second molecule using Local Global Alignment Scoring function (LGA_S) analysis.

The Longest Continuous Segments (LCS) analysis determines percent of residues (longest continuous segment) that can fit under cutoff of root mean square (RMSD) cutoff.

The Global Distance Test (GDT) analysis determines percent of residues (largest set, not necessary continuous) that can fit under the cutoff of distance between residues which might be either contiguous or non-contiguous.

The LGA_S scoring function combines the results of LCS and GDT.

Because multiple terms are not defined in the specification (see rejections under 35 U.S.C. 112, second paragraph, sections B)-C)), Examiner is not able to conduct full search of prior art. Thus, the following art rejection addresses the general idea of the invention, namely fulfilling not only RMSD restrictions, but also including

distance restrictions in evaluating 3D similarities between structure of two protein molecules. As stated by applicant, "the scope of the invention is not intended to be limited to the particular forms disclosed and the invention covers all modifications, equivalents, and alternatives falling within the spirit and scope of the invention as defined by the claims" (p. 9, paragraph [0015]).

Claims 1,2,4-7,10-13 are rejected under 35 U.S.C. 102(b) as anticipated by Lackner et al (reference submitted by applicant). Lackner describes method of finding 3D similarities between protein structures using ProSup algorithm which determines segments that can fit under RMSD cutoff (i.e., the approach addressed in the instant application as Longest Continuous Segments (LCS) analysis). In the course of this analysis Lackner also uses distance limitations which introduce distance cutoff for alignment construction. See Table 1, and discussion of parameters d_c and d_e on p. 747. Although the instant method addresses distance as being between not necessarily contiguous segments of residue pairs, it also reads on using distance cutoff for contiguous residues as well. For the latter embodiment, the referenced method reads on the instant method as claimed.

With regard to claims 4,10, Lackner's method is used regardless to sequence similarity.

With regard to claims 5,11,13,intended use limitation does not impart patentability of claims.

Conclusion.

No claims are allowed

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Michael Borin, Ph.D.

Primary Examiner

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mlb